



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

Population Assessment of Tobacco and Health (PATH) Study – Fourth Wave of Data Collection

AGENCY: National Institute of Health, HHS.

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on April 15, 2016, pages 22290 – 22291 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget,

Office of Regulatory Affairs, OIRA_Submission@omb.eop.gov or by fax to (202) 395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing or request more information on the proposed project, contact: Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Boulevard, Room 5185; or call non-toll-free number (301) 443-8755; or E-mail your request, including your address to: PATHprojectofficer@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Population Assessment of Tobacco and Health (PATH) Study – Fourth Wave of Data Collection (NIDA), 0925-0664, expiration date 8/31/2018 – REVISION – NIDA, NIH, in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a revision request (OMB number 0925-0664, expiration date 8/31/2018) for the Population Assessment of Tobacco and Health (PATH) Study to conduct the fourth wave of data collection. The PATH Study is a large national longitudinal cohort study on tobacco use behavior and

health among the U.S. household population of adults age 18 and older and youth ages 12 to 17. On an annual basis, the PATH Study conducts interviews with and collects biospecimens from adults and youth to help inform the development, implementation, and evaluation of tobacco-product regulations by FDA in meeting its mission under the Family Smoking Prevention and Tobacco Control Act (TCA) to regulate tobacco products, including tobacco-product advertising, labeling, marketing, constituents, ingredients, and additives. The longitudinal design of the PATH Study provides it with the capacity to measure and report within-person changes and between-person differences in tobacco product use behaviors and health effects within the cohort over time. These data will help to inform regulatory decisions and actions by FDA and FDA's evaluations of associations between its regulations and tobacco use behaviors and health indicators in the population.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 94,798.

Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)	Total Annual Burden Hours
1. Household Screener	Households	48,018	1	14/60	11,204
2. Individual Screener	Adults – New adults	9,152	1	6/60	915
3. Extended Interview	Adults – New adults and Wave 1 youth respondents who age up to adult cohort at	10,737	1	68/60	12,169

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)	Total Annual Burden Hours
Wave 4					
4. Extended Interview	Adults – Adult respondents at previous wave	23,414	1	1	23,414
5. Parent Interview	Adults - Parents of new youth and parents of shadow youth who age up to youth cohort at Wave 4	6,561	1	19/60	2,078
6. Parent Interview	Adults – Parents of youth respondents at previous wave	8,800	1	16/60	2,347
7. Extended Interview	Youth – New youth and shadow youth who age up to youth cohort at Wave 4	6,432	1	45/60	4,824
8. Extended Interview	Youth – Youth respondents at previous wave	8,627	1	35/60	5,032
9. Tobacco Use Form	Adults	23,133	1	5/60	1,928
10. Tobacco Use Form	Youth	10,239	1	5/60	853
11. Shadow Youth Only Screener	Households	41,207	1	5/60	3,434
12. Verification Interview	Adults	33,889	1	2/60	1,130
13. Validation Interview	Adults	301	1	4/60	20
14. Biospecimen Collection: Blood	Adults – New adults and Wave 1 youth	4,832	1	18/60	1,450

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)	Total Annual Burden Hours
	respondents who age up to adult cohort at Wave 4				
15. Biospecimen Collection: Urine	Adults	18,301	1	10/60	3,050
16. Biospecimen Collection: Urine	Youth	10,239	1	10/60	1,707
17. Follow-up/Tracking Participant Information Form	Adults	34,151	2	8/60	9,107
18. Follow-up/Tracking Participant Information Form for Youth (completed by parents)	Adults – Parents of youth respondents	15,059	2	8/60	4,016
19. Follow-up/Tracking Participant Information Form for sample shadow youth (completed by parents)	Adults – Parents of shadow youth	4,684	2	8/60	1,249
20. Consent for Extended Interview	Adults – New adults and Wave 1 youth respondents who age up to adult cohort at Wave 4	13,984	1	4/60	932

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)	Total Annual Burden Hours
21. Parent Permission and Consent for Parent Interview	Adults – Parents of new youth and parents of Shadow youth who age up to youth cohort at Wave 4	7,657	1	5/60	638
22. Assent for Extended Interview	Youth – New youth and shadow youth who age up to youth cohort at Wave 4	7,657	1	3/60	383
23. Consent for Biological Samples	Adults – New adults and Wave 1 youth respondents who age up to adult cohort at Wave 4	10,737	1	5/60	895
24. Parent permission for urine collection	Adults – Parents of youth respondents at previous wave	15,360	1	3/60	768
25. Assent for urine collection	Youth	15,059	1	5/60	1,255
Total		388,229	442,123		94,798

Dated: June 27, 2016.

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